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Reply Brief

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: KARL-LUTZ LAUTERJUNG	§	Group Art Unit: 3738
Serial No.: 08/878,908	§	Examiner: P. Prebilic
Filed: June 19, 1997	§	
For: PROSTHETIC REPAIR OF BODY PASSAGES	§	Atty. Dkt. No.: SULZ-0005-US

Commissioner for Patents
Board of Patent Appeals & Interferences
Washington, D.C. 20231

BRIEF TRANSMITTAL

Sir:

Transmitted herewith in triplicate is the Reply Brief in this application with respect to the Notice of Appeal filed on September 22, 2000.

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 20-1504. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Date: 2/23/00

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Date of Deposit: 2-23-01
I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to the Commissioner for Patents, Washington DC 20231.
Azilda Marcel Authement

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Acknowledged PBP 3/8/01

REPLY BRIEF

Sir:

In response to the Examiner's answer mailed January 11, 2000, the applicant hereby responds to the new issues raised by the Examiner.

Unfortunately, the Examiner and the applicant have grouped the issues differently which may result in some added complexity. In an effort to facilitate review of this matter, the applicant will respond to the issues as positioned by the Examiner.

ISSUE 1

Examiner's Issue 1 is whether claims 1 through 25 and 28 are anticipated under section 102b by the Lazarus disclosure.

The Examiner refers to Figures 3 and 4 which show a ring shaped staple having prongs 71 and 70.

Claim 21

Claim 21 calls for a pair of folded, resilient annular springs. These annular springs are positioned on the ends of a

tubular graft. Thus, each end of the tubular graft has a spring. Each spring is defined as being folded, resilient and annular.

Also claimed is a first pair of loops extending in one direction and a second pair of loops in the opposite direction. As the Examiner correctly points out in the second full paragraph of page 6, each of the loops is defined by the claimed fold. In other words, referring to Figure 2, the fold occurs along the line B-B creating a pair of loops (having tips A) extending upwardly therefrom and a second pair of loops extending downwardly. Thus, the claim calls for a spring that is annular or ring-shaped. Moreover, that spring must in turn be folded so as to create the two opposed pairs of loops.

The Examiner avoids explaining exactly where the folds are in the cited reference. The Examiner argues that any reasonable examiner would see folds. But, it is respectfully submitted that the reason for finessing the point is that the Examiner plainly understands that what he is referring to as folds are actually bends of wire. However as the Examiner expressly points out, the claim calls for the annular springs themselves to be folded, not for an internal portion of the springs to be bent. In fact, the Examiner is ignoring the claim requirement, at the macro or spring level, that the entire spring must be folded to have two opposed pairs of loops.

It is impossible for the applicant to guess where the folds are alleged to lie in the cited Lazarus reference. Presumably, the Examiner would point one of the bent prongs 70, 71 or the individual corrugated bends within the staple. However, it is clear that the overall staple is not itself folded as claimed.

Claim 22

Claim 22 calls for a second pair of loops that are arranged to avoid occlusion of the renal arteries when the prosthesis is positioned in the abdominal aorta. This is shown in Figure 4. There it can be seen that the loops are positioned so that the passages 50 and 52 are left free and open. This is a result of the folded configuration of the spring.

There is simply no indication whatsoever that the Lazarus device could be folded in this fashion. Certainly whatever it is that the Examiner claims are folds inside the staple of Lazarus do not help to avoid occlusion of the renal arteries. A macro level folding of the spring in the applicant's invention allows the device to be firmly positioned without occluding the renal arteries. The internal or micro level bends in Lazarus fail to assist in achieving this claimed feature.

The Examiner also argues that the claimed configuration is merely a statement of intended use. But the claim clearly covers the corresponding structure. Pac-Tec, Inc. v. Amerace Corp., 903 F.2d 796 (Fed. Cir. (1990) (Argument that "adapted to" does not raise a structural limitation is "frivolous" in view of In re Venezia); In re Venezia, 189 U.S.P.Q. 149, 150-1 (C.C.P.A. 1976) ("this language [adapted to] imparts a structural limitation"). That is, the claim covers that structure which allows the device to be positioned so that does not occlude the renal arteries. It is very difficult to see how the alleged folds in Lazarus somehow help to keep the renal arteries clear if the device were positioned in the location shown in Figure 4.

We do not know how the Lazarus staple would operate if folded or if it even could be folded. It could bow inwardly, it

may refuse to bow outwardly, it may not hold its position and simply compress radially. It seems most likely that it would compress radially. There is simply no reason to believe that Lazarus' staple would even be capable of folding as claimed in claim 22.

Claim 23

Claim 23 calls for annular springs that have an unfolded diameter and a tubular graft that has an unfolded diameter less than the unfolded diameter of one of the annular springs.

Lazarus does not have an unfolded diameter. Its diameter is presumably defined by its internal bends that never change. Those bends do not change the diameter of the overall staple. Therefore, Lazarus does not have an unfolded diameter which is any different than its allegedly folded diameter. Thus, there is no reason to suggest that Lazarus' tubular graft has a diameter less than the unfolded diameter of one of the staples.

The Examiner refers to Figure 6 of Lazarus and states that "the staple is still folded and within the tubular graft". The Examiner reasons that "if the staple were stretched out radially so it no longer has folds in it" "the staple would have a diameter greater than the compressed diameter of the tubular graft". Again, the Examiner is referring to the bends not the macro folds of the overall spring.

The problem is that the Lazarus does not have an unfolded diameter, it was never intended to be unfolded, it was never designed to be unfolded and therefore it simply has no unfolded diameter anywhere except in the Examiner's imagination. It is improper to reconstruct and redesign the cited reference to attempt to meet the claimed limitations.

In view of these remarks all of the rejections should be reversed.

ISSUE 2

The points made above respond to the Examiner's positions with respect to the Robinson reference and claim 21.

Claim 22

With respect to claim 22, the Examiner suggests that somehow the applicant's arguments transform the claim into a means plus function claim. In re Venezia (cited in response to Issue 1) holds that claims that are written in the format of a item "to" do something are interpreted to incorporate the structure needed to accomplish the recited action.

Further, the Examiner argues that Robinson shows the structure in the exact location referred to in claim 22. However, nothing in Robinson suggests that the device is specifically positioned adjacent the renal arteries. Perhaps Robinson never mentioned such a structure because Robinson would occlude those arteries as designed.

The claim is more specific than simply calling for not occluding the arteries. The claim describes a specific structure of loops that are arranged about a fold so as to avoid occluding the arteries. In particular, the loops can extend upwardly between the arteries on each side, bridging the region between the renal arteries (on two sides). At the same time, the region between the loops defines openings that allow for free access to the renal arteries. Without the looped configuration, Robinson can not achieve the claimed structure.

The Examiner somehow contends that Robinson would be non-functional if it did not achieve the claimed invention.

Certainly, this is overargument since Robinson may do all kinds of things, some not quite as well as the claimed invention.

Claim 22 calls for a second pair of loops arranged to avoid occlusion of the renal arteries when the prosthesis is positioned in the abdominal aorta. Since Robinson does not include a second pair of loops or any loops or even a fold, the Examiner must essentially read the second pair of loops out of the claim. But this is the problem with all the rejections discussed herein. The Examiner reads the claims impermissibly broadly and then asserts that they are anticipated. There is no indication that Robinson's "loops", if he had such loops, could somehow be utilized to avoid occlusion.

Claim 23

The argument with respect to claim 23 suffers from the same infirmities. Claim 23 calls for annular springs having an unfolded diameter, the tubular graft having a diameter less than the unfolded diameter of one of the annular springs. The diameter of the tubular graft is the same whether it is crunched up or not. Similarly, the alleged spring has a set diameter as well.

As can plainly be seen in the Figure 15 referred to by the Examiner, both Robinson elements have exactly the same diameter. The Examiner suggests that the compressed end is somehow significant. However, even if one looks at the Robinson device as compressed, when compressed, the diameters of the so-called spring and the graft are the same.

Similarly the Examiner contends that the uncompressed end could be further expanded. But, the Examiner cannot redesign the Robinson structure. The Robinson device has a diameter, and Robinson does not suggest unbending the bends. Robinson

does not have a shape other than the zigzag configuration shown. Therefore, Robinson does not teach a structure in which the diameters of the so-called spring and graft are different.

ISSUE 3

Claim 63

The first issue raised under issue number 3 was with respect to claim 63. The Examiner provides his own definition of a wire. However as defined by the Examiner, the wire must be "pliable". Pliable means "bent easily; flexible; pliant; flexible in disposition; easily persuaded; adaptable". See the Living Webster Encyclopedic Dictionary of the English Language (1971).

The flat spring stents 18 and 20 disclosed in Kwan-Gett are not pliable. They are designed to be stiff and therefore are not easily bent. The stents 18 and 20 are described as "stiffening members". See column 5, lines 7-12. They are expressly to provide "for stiffening the cylindrical wall". See column 5, line 45.

In contrast, the claimed invention uses a bundle of wires, each wire being pliable by itself. They obtain stiffness by being wrapped concentrically about one other. However, the wire itself is pliable as pointed out by the Examiner.

Therefore, Kwan-Gett does not teach a "wire" even taking the Examiner's own definition (never asserted during prosecution). Thus, the rejection of claim 63 should be reversed.

Claim 65

With respect to the rejection of claim 65 (dependent on claim 63), for the first time, the Examiner claims that the

limitations of claim 65 are inherently present in Kwan-Gett. Claim 65 calls for a ring comprising a bundle of overlapping wires formed of a strand of resilient wire, said ring secured to said graft adjacent to one of the free ends thereof, wherein the minimum diameter of said ring is less than that of a solid ring of the same dimensions.

To make out an inherency rejection the Examiner must show that there is no other permissible reading of the cited art other than one that meets the claimed limitation. Thus, the reference must "necessarily" have the claimed feature. See MPEP § 2131.01. The Examiner contends that just because the reference uses deformable material, its minimum diameter must be less than that of a solid ring of the same dimensions.

On appeal the Examiner simply redefines the minimum bending diameter in a manner that is totally inconsistent with the specification. Now for the first time, he argues that "minimum bending diameter" actually means "bending force". This of course makes no sense.

The Examiner contends that the applicant's design or operation is wrong and that the Examiner would substitute a better design. However, the Examiner is forced to examine what the applicant considers his invention, not what the Examiner would consider to be a better invention. The Examiner's proposition that "the controlling dimension for bending is really the cross-sectional area" simply misses the boat. The issue is not bending force, it is minimum bending diameter.

The Examiner contends that a solid ring "requires a higher bending force". But even if that were so, it is totally irrelevant to the claimed invention. The claimed invention relates to minimum bending diameter. The Examiner ignores this

limitation and redefines the invention to be bending force because he apparently believes that is what the applicant should have claimed. As a result, the examination of claim 65 is fatally flawed.

The minimum bending diameter is the minimum bending diameter around which the wire can be bent without plastic deformation. See specification at page 8, lines 30-33. Thus, each of the individual strands of wire have a very small individual minimum bending diameter. However, the composite of all the wires may have substantial spring stiffness in some embodiments. Thus, the idea is to have a plurality of windings of wire which have a minimum bending diameter which is small and contributes this property to the composite.

No evidence whatsoever suggests that this property inheres in the torsional spring of Kwan-Gett. Because the flat bands are simply stacked one on top of the other, it is not seen why the minimum bending diameter of the composite would be any different from that of any one of the individual bands. That is, if the flat torsional spring is bent about its own plane, the composite would have the same minimum bending diameter as each of the individual bands because each of the bands is effectively in parallel.

In contrast, in the claimed invention, a bundle of overlapping windings can be formed in a way that contributes a lower composite minimum bending diameter. This may be in part due to the shape of the wire utilized or the way the wire is wrapped to form a plurality of overlapping wires to form a bundle, as examples, such that the individual wires can contribute to a low composite minimum bending diameter compared to a solid shape of the same composite dimensions.

Normally, the composite would have a much higher minimum bending diameter. Thus, the applicant appreciated that by creating a wrapped bundle of overlapping windings, the composite could be made to exhibit low minimum bending diameter making the composite useful for tight applications(such as intravenous applications).

There is no reason to believe that a torsional spring composed of a stacked wrap of flat bands, when bent transverse to its plane would have any different minimum bending diameter. The only way minimum bending diameter would make any sense would be to bend the ring transversely to its plane. Simply compressing the spring within the plane, would not show any type of bending diameter.

Thus, to achieve a structure that has lower minimum bending diameter due to the use of wires, the wires would have to be pliable, they would have to be shaped in a way that enables them to bend readily in a direction transverse to the plane of the ring, and they would have to be arranged so that they overlap in a fashion that they would not just simply all be bent in parallel to one another. Each of these features is no where present in the Kwan-Gett reference. Thus, there is simply no reason to suspect that Kwan-Gett would exhibit the claimed property.

Therefore, the rejection of claim 65 should be reversed.

Respectfully submitted,

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